

supplemental applications received during FY 2004 are reviewed within 320 days.

Manufacturing supplemental animal drug applications and reactivations of such supplemental applications received during FY 2004 are reviewed within 225 days.

Investigational animal study submissions received during FY 2004 are reviewed within 320 days.

Investigational animal drug submissions of protocols, that the Agency and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an animal drug application or supplemental animal drug application, without substantial data received during FY 2004 are reviewed within 125 days.

Administrative NADAs received during FY 2004 are reviewed within 90 days.

*FY 05—90 percent of:*

NADAs and reactivations of NADAs received during FY 2005 are reviewed within 270 days.

Non-manufacturing supplemental animal drug applications and reactivations of such supplemental applications received during FY 2005 are reviewed within 285 days.

Manufacturing supplemental animal drug applications and reactivations of such supplemental application received during FY 2005 are reviewed within 190 days.

Investigational animal drug study submissions received during FY 2005 are reviewed within 285 days.

Investigational animal drug submissions consisting of protocols, that the Agency and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an animal drug application or supplemental animal drug application, without substantial data submissions received during FY 2005 are reviewed within 100 days.

Administrative NADAs received during FY 2005 are reviewed within 85 days.

*FY 06—90 percent of:*

NADAs and reactivations of NADAs received during FY 2006 are reviewed within 230 days.

Non-manufacturing supplemental animal drug applications and reactivations of such supplemental applications received during FY 2006 are reviewed within 235 days.

Manufacturing supplemental animal drug applications and reactivations of such supplemental applications received during FY 2006 are reviewed within 140 days.

Investigational animal drug study submissions received during FY 2006 are reviewed within 235 days.

Investigational animal drug submissions consisting of protocols, that the Agency and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an animal drug application or supplemental animal drug application, without substantial data submissions received during FY 2006 are reviewed within 80 days.

Administrative NADAs received during FY 2006 are reviewed within 80 days.

*FY 07—90 percent of:*

NADAs and reactivations of NADAs received during FY 2007 are reviewed within 200 days.

Non-manufacturing supplemental animal drug applications and reactivations of such supplemental application received during FY 2007 are reviewed within 200 days.

Manufacturing supplemental animal drug applications and reactivations of such supplemental applications received during FY 2007 are reviewed within 120 days.

Investigational animal drug study submissions received during FY 2007 are reviewed within 200 days.

Investigational animal drug submissions consisting of protocols, that the Agency and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an animal drug application or supplemental animal drug application, without substantial data submissions received during FY 2007 are reviewed within 60 days.

Administrative NADAs received during FY 2007 are reviewed within 70 days.

*FY 08—90 percent of:*

NADAs and reactivations of NADAs received during FY 2008 are reviewed within 120 days.

Non-manufacturing supplemental animal drug applications and reactivations of such supplemental applications received during FY 2008 are reviewed within 180 days.

Manufacturing supplemental animal drug applications and reactivations of such supplemental applications received during FY 2008 are reviewed within 120 days.

Investigational animal drug study submissions received during FY 2008 are reviewed within 180 days.

Investigational animal drug submissions consisting of protocols, that the Agency and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an animal drug application or supplemental animal drug application, without substantial data submissions received during FY 2008 are reviewed within 50 days.

Administrative NADAs received during FY 2008 are reviewed within 60 days.

#### WORKLOAD ADJUSTMENT

The Animal Drug User Fee Act of 2003, requires FDA to annually adjust fee revenues after FY 2004 to reflect changes in review workload utilizing a weighted average of animal drug applications, supplemental animal drug applications for which data with respect to safety or effectiveness are required, manufacturing supplemental animal drug applications, investigational animal drug study submissions, and investigational animal drug protocol submissions. The Agency currently intends to utilize the method detailed below to calculate the workload adjustment, and the percent increase in fees will be the amount of the sum of the output from the workload adjuster that is greater than one (1.0). However, the weighting of the specific factors may change in light of discussions with the animal drug industry and the results of ongoing activity based costing analyses within the Center for Veterinary Medicine.

The term "workload adjuster" applicable to a fiscal year consists of the sum of the following 5 components:

(A) The percent of change in the total number of original and reactivated animal drug applications submitted (comparing the three-year average number of such submissions for fiscal year 2001-2003 to the three-year average for the most recent three year period ending June 30 before the start of the fiscal year) times 3 percent.

(B) The percent of change in the total number of original and reactivated supplemental animal drug applications for which data with respect to safety or effectiveness are required (comparing the three-year average number of such submissions for fiscal year 2001-2003 to the three-year average for the most recent three year period ending June 30 before the start of the fiscal year) times 12 percent.

(C) The percent of change in the total number of original and reactivated manufacturing supplemental animal drug applications (comparing the three-year average number of such submissions for fiscal year 2001-2003 to the three-year average for the

most recent three year period ending June 30 before the start of the fiscal year) times 25 percent.

(D) The percent of change in the total number of investigational animal drug study submissions (comparing the three-year average number of such submissions for fiscal year 2001-2003 to the three-year average for the most recent three year period ending June 30 before the start of the fiscal year) times 46 percent.

(E) The percent of change in the total number of reviewed investigational animal drug protocol submissions (comparing the three-year average number of such submissions for fiscal year 2001-2003 to the three-year average for the most recent three year period ending June 30 before the start of the fiscal year) times 14 percent.

#### THE VA-HUD APPROPRIATIONS BILL AND THE DEFENSE AUTHORIZATION CONFERENCE REPORT

Mr. JEFFORDS. Mr. President, hardly a day goes by without an announcement of new casualties in Iraq, a news story about the family of a fallen service member, or the profile of a heroic soldier learning to cope with the aftermath of wounds suffered in Iraq. While the conflict is Iraq prompts quick approval of the defense spending bills, there is less appreciation for mounting costs to the Department of Veterans Affairs.

I was most distressed at last month's refusal by the White House to support the Senate's addition to the Iraq-Afghanistan emergency supplemental of \$1.3 billion in funding for veterans' health care. Most Senators understand that military activities in Iraq are significantly increasing the burden on the VA, and supported the addition of \$1.3 billion to the Iraq supplemental. Seeing that this amendment was poised for inclusion in the final bill, the White House sent notice to Congress that it would veto the entire package if money for the VA were included. Sadly, Congress gave in to administration pressure and removed this critical funding.

I am pleased that the Senate leadership finally saw fit to bring the VA-HUD appropriations bill to the Senate floor this week. This critical legislation, setting funding levels for fiscal year 2004, which actually began 6 weeks ago, is long overdue. This legislation provides \$62 billion for the Veterans Administration, \$27 billion of which goes to the Veterans Health Administration, an increase of \$3.9 billion over last year's spending level and \$1.3 billion over the President's request. Because of budget constraints and the unwillingness of the administration to endorse additional funding for the VA, the Senate Appropriations Committee designated the additional \$1.3 billion as emergency spending so as not to count against the annual spending caps. However, this also made the increase subject to the President's approval, and it risked meeting the same fate as other increases rejected by President Bush.

I am very pleased that during debate on the VA-HUD appropriations bill, the

managers successfully offered an amendment to remove the emergency designation and incorporate the \$1.3 billion into the bill, thereby greatly increasing the chances that this money will actually get to veterans this year. It seems that a majority of Senators have been listening to the few of us who have been decrying the state of VA funding for some time, and they are now coming to understand that even these modest increases do not make up for the continual shortfall experienced by the VA in recent years. It's long past time that this trend be reversed.

The Senate VA-HUD appropriations bill also supports the Rural Health Initiative, RHI, a successful examination of innovative methods of delivering health care to veterans in rural areas. The VA must become more adept at spreading its health care dollars further across rural America. I am encouraged that the RHI will help improve the VA's performance in this area.

After making significant progress on this legislation, I was discouraged that the Senate leadership decided to pull this VA-HUD bill off the floor prior to its completion in order to begin a 30-hour discussion of the status of judicial nominations. While I agree that judicial nominations are important, I was most disappointed that a largely partisan political debate took precedence over the completion of much needed funding for veterans. I urge the leadership to quickly bring us back to the people's business—the work we were sent here to accomplish.

I would like to mention another issue of concern to veterans that came before the Senate this week. For years I have been a primary promoter of concurrent receipt—the payment to disabled veterans of the full disability and retirement benefits to which they are entitled. For many years, disabled military retirees have been forced to choose between receiving their full retirement pay or their disability benefits. This injustice has finally been recognized by a majority of the Congress, in large part due to the unflagging commitment of Senator HARRY REID. In recent years, Congress has moved to partially restore these benefits. The fiscal year 2004 Defense authorization conference report contains legislation allowing combat disabled veterans with a disability greater than 10 percent to receive their full disability and retirement benefits. It also provides for a 10-year phase-in of full disability and retirement benefits for those with a noncombat related disability rating of over 50 percent.

While I am pleased to see this important improvement in benefit payments, I am concerned that some might view this as the end of the road for this issue. I intend to work closely with Senator REID to continue to press the administration and the Congress to fully fund concurrent receipt for all disabled veterans. This is a basic principle of fairness that is not rectified by halfway measures.

I regret that, for a number of reasons, I was unable to support passage of the Defense authorization conference report, despite its progress on concurrent receipt. Unfortunately, the legislation included unacceptable environmental provisions. As a former Navy Officer and 30-year reservist, I understand the need for the best possible military training. As the ranking member of the Environment and Public Works, EPW, Committee, I was quite concerned by a request from the Bush administration to exempt the Department of Defense, DoD, from five of our Nation's most important and effective environmental laws. After careful review by the EPW Committee, I was convinced that the waivers contained in current law are quite sufficient to provide flexibility for DoD if it needs greater leeway to conduct military readiness exercises.

In an effort to forge a reasonable compromise between DoD's request and sound environmental policy, Senator LAUTENBERG and I authorized as amendment to the defense authorization bill that was supported by a majority of Senators. While this amendment carefully balanced the Defense Department's need for training with the Interior Department's mandate to protect endangered species, it was dropped in conference with the House of Representatives. In its place, the conferees added language providing DoD with broad authority to sidestep the Endangered Species Act and the Marine Mammal Protection Act, even dropping requirements that any waivers be related to military readiness. I cannot in good conscience support legislation that undermines such critical environmental legislation. Therefore, I had no choice but to vote against the defense authorization conference agreement in spite of its improvement on concurrent receipt.

Mr. President, we have a long way to go before our veterans health system is fully funded and before veterans receive the full compensation they deserve for their years of service to the Nation. I hope that the daily stories of heroism coming out of Iraq will compel more Members of Congress to stand with the veterans and not to rest until justice is done.

#### VETERANS DAY

Mr. GRAHAM of Florida. Mr. President, I rise to recognize the significance of Veterans Day and to honor the Americans it celebrates. On Veterans Day we pay tribute to the men and women who have fought for our freedom and those who continue to do so right now—they are far from their homes and families, striving to keep us safe from terrorism. These service-members exemplify what it means to be an American—courage, selflessness, and a deep love of and commitment to his or her fellow countrymen.

First proclaimed by President Wilson in 1919, Veterans Day was initially

known as Armistice Day and was intended to commemorate the armistice between the Allies and Central Powers that ended the fighting of World War I. In 1953, a Kansas citizen named Alvin King lobbied to change the holiday's name to honor all veterans, not just those from World War I. On June 1, 1954, President Eisenhower signed into law an act proclaiming November 11 to be Veterans Day. Yesterday, we celebrated the 50th anniversary of that celebration.

There are currently 25 million American veterans. Every day more and more service-members return home from Iraq and Afghanistan becoming new members of that elite group of citizens. These heroic Americans freely offer their lives to protect those they leave behind, and those they've never even met. For this sacrifice, we owe them our continued support and care.

Unfortunately, the Bush administration has established a disturbing pattern of behavior that seriously undercuts this long-held ideal. In the past 2 years, the President has been full of patriotic words and speeches—rhetoric that has proven hollow. At a time when 133,000 service-members celebrated their Veterans Day in the deserts of Iraq, the Administration continues to undermine our veterans' ability to receive the quality health care they have earned. With the recent Iraq supplemental spending bill, the administration took an opportunity to demonstrate its commitment to our troops and twisted it into another way to short-change our veterans.

In that appropriations bill, my Senate colleagues and I worked hard to secure an additional \$1.3 billion for VA healthcare. These desperately needed funds were subsequently removed at the insistence of the Bush Administration. Nationwide, 80,000 veterans—including more than 10,000 in my home State of Florida alone—are forced to wait longer than 6 months to see a VA doctor. When the service-members currently serving in Iraq return home and become veterans, they will be entitled to 2 years of priority VA health care after they have separated from military service. This added influx of patients, when coupled with the administration's refusal to give VA the money it needs to care for them, will only strain the system further.

During debates on that same supplemental spending bill, my fellow Democrats and I joined together to offer an amendment that would have helped rectify a longstanding inequity in the retirement pay our veterans receive—or, should I say, don't receive. Currently, the earned retirement pay of veterans who are both disabled and eligible for military pensions is reduced simply because they receive disability benefits as well. This practice of denying concurrent receipt does not apply to other Federal workers, only to the courageous men and women like the ones currently serving overseas, who made the armed services their careers.